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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/612,298	07/02/2003	Byron E. Anderson	093073-9001	093073-9001 5133	
	23510 7590 06/05/2007 MICHAEL BEST & FRIEDRICH, LLP			EXAMINER	
ONE SOUTH PINCKNEY STREET			GROSS, CHRISTOPHER M		
	P O BOX 1806 MADISON, WI 53701			PAPER NUMBER	
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			06/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/612,298	ANDERSON, BYRON E.				
Office Action Summary	Examiner	Art Unit				
-	Christopher M. Gross	1639				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  BEGON THIS COMMUNICATION  BETT THIS COMMUNICATI	ON.  timely filed  om the mailing date of this communication.  NED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 03 Ja	Responsive to communication(s) filed on <u>03 January 2007</u> .					
· <u> </u>	<i>,</i> —					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-45 is/are pending in the application.						
4a) Of the above claim(s) <u>1-4 and 10-42</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 5-9 and 43-45 is/are rejected.						
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.						
are subject to restriction and of	ojostion requirement.					
Application Papers						
9) The specification is objected to by the Examine						
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
		55 7 1611011 57 161111 1 1 1 5 1 1 5 2 .				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.						
Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summa					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	_	· / 言 · · · · · · · · · · · · · · · · ·				

#### **DETAILED ACTION**

Responsive to communications entered 1/3/2007. Claims 1-45 are pending. Claims 1-45 are pending. Claims 1-4, 10-42 are withdrawn. Claims 5-9, 43-45 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is again acknowledged: this application claims priority to provisional application 60/394176 (filed 7/3/2002).

# Withdrawn Objection(s) and/or Rejection(s)

The objection to claims 44 and 45 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 5-9, 43-45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's arguments and amendments to the claims.

# Maintained Claim Rejection(s) - 35 USC § 102

Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Dooley et al (1994 Science 266:2019-2022).

## Response to Arguments

The declaration under 37 CFR 1.132 filed 1/3/2007 is insufficient to overcome the rejection of claims 5-9 based upon Dooley et al under 35 USC 102 (b) as set forth in the last Office action because:

Applicant argues, see p 5 (1/3/2007) that Dooley et al do not teach all elements and in accompanying said declaration under 37 CFR 1.132, applicant asserts that the Ac-rtfwyxx-NH<sub>2</sub> peptide mixture of Dooley et al does not represent the entirety of a library, but rather represents a mere subset thereof.

It is noted, however, such a narrow view of what constitutes a library is not supported by the present specification.

Applicant claims a "library" of compounds; however, solely to rebut applicant's arguments, the term is used quite broadly in the art to mean "any ensemble of molecules" (e.g., see Janda, K. D. "Tagged versus untagged libraries: Methods for the generation and screening of combinatorial chemical libraries" PNAS USA November 1994, 91, 10779-10785, especially page 10779, column 1, last sentence, "In its purest form, a combinatorial chemical library can be defined as any ensemble of molecules"). As there is no specific definition of a library in Applicants' specification, any ensemble of molecules that reads on those set forth in the claims is deemed to be a library. As such the Ac-rtfwyxx-NH<sub>2</sub> mixture of Dooley et al clearly read on those claimed as set forth supra, the reference is deemed to disclose a "library".

In conclusion, applicant's arguments and evidence is not commensurate in scope with the claims. See MPEP § 716.

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Additionally, it is noted the recitation 'a library' occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinilla et al (1998 J. Mol Biol 283:1013-1025 – IDS entry 4/11/2006).

#### Response to Arguments

The declaration under 37 CFR 1.132 filed 1/3/2007 is insufficient to overcome the rejection of claims 5-8 based upon Pinilla et al under 35 USC 102 (b) as set forth in the last Office action because:

Applicant argues, see p 5 (1/3/2007) that Pinilla et al do not teach all elements and in accompanying said declaration under 37 CFR 1.132, applicant asserts that the table 1 of Pinilla et al does not represent a library, because the peptides are not mixed together in a single vessel.

It is noted, however, such a narrow view of what constitutes a library is not supported by the present specification.

Applicant claims a "library" of compounds; however, solely to rebut applicant's arguments, the term is used quite broadly in the art to mean "any ensemble of

molecules" (e.g., see Janda, K. D. "Tagged versus untagged libraries: Methods for the generation and screening of combinatorial chemical libraries" PNAS USA November 1994, 91, 10779-10785, especially page 10779, column 1, last sentence, "In its purest form, a combinatorial chemical library can be defined as <u>any ensemble of molecules</u>"). As there is no specific definition of a library in Applicants' specification, any ensemble of molecules that reads on those set forth in the claims is deemed to be a library. As such, table 1 of Pinilla et al clearly read on those claimed as set forth supra, the reference is deemed to disclose a "library".

In conclusion, applicant's arguments and evidence is not commensurate in scope with the claims. See MPEP § 716.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the peptides species are mixed together in one vessel) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

# Maintained Claim Rejection(s) - 35 USC § 103

Claims 5-9, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of **Dooley et al** (1994 Science 266:2019-2022) or **Pinilla et al** (1998 J. Mol. Biol. 283:1013-1025 – IDS entry 4/11/2006) in view of either of **Lam et al** (1991 Nature 354:82-84) or **Lebl et al** (1995 Biopolymers 37: 177-198 – IDS entry 4/11/2006).

Claims 5-9 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dooley et al** (1994 Science 266:2019-2022) in view of **Satoh et al** (1998 Analytical Biochemistry 260:96-102).

#### Response to Arguments

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Specifically, Applicant argues, see p 6 (1/3/2007) that neither Dooley or Pinilla teach a library.

However, as discussed above, giving the claims the broadest reasonable interpretation, the Ac-rtfwyxx-NH<sub>2</sub> mixture of Dooley et al and peptides set forth in table 1 of Pinilla both represent a type of library, therein all elements are taught in combinations concerning **Lam et al** or **Lebl et al** as well as **Satoh et al**.

## New Claim Rejection - 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This rejection is necessitated by Applicant's amendment to the claims.

Claims 5-9, 43 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 45 has been amended to include the D peptide library set forth in claim 5 on a microtiter plate.

The specification as originally filed provided no implicit or explicit support for a library of the breadth set forth in claim 5-9 on a microtiter plate. A microtiter plate is taken as a type of solid support as set forth in claim 43.

It is noted that claim 45 as originally filed, being dependent from claim 31, was drawn to a method of reducing the ConA lectin binding to at least one of its receptors comprising delivering to the mammal a D-peptide comprising a pentapeptide core selected from the group consisting of Xaa<sub>1</sub>YYFF and Xaa<sub>1</sub>FYFF wherein Xaa<sub>1</sub> is an amino acid of the D- or L-configuration independently selected from the group consisting of D, E, K, R, H, N, Q, C, S, T, G, A, V, L, I, M and P; said narrower pentapeptide cores were attached to a microtiter plate.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3<sup>rd</sup> paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a

claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross Examiner Art Unit 1639

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J.) S. hydr J. DOUGLAS SCHULTZ, PH.D. SUBERVISORY PATENT EXAMINER